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EXAMINER	
CAMPBELL, VICTORIA P	

ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,473	POTTER ET AL.	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-36 and 38-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-9,11-14,16-19,26-36,38-43,45-52 and 57-59* is/are rejected.

7)☒ Claim(s) *10,15,20-25,44 and 53-56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the second Office Action based on the 10/523473 application filed January 3, 2006. Claims 1, 2, 4, 5, 7-36, and 38-59 as amended August 26, 2009 are currently pending and considered below.

Drawings

1. The drawings were received on August 26, 2009. These drawings are accepted.

Claim Objections

2. Claim 58 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding the above claims, applicant has amended claim 1 to include new language under part (iii) which calls for a lower barrel and the upper barrel. Claim 2 also calls for an upper barrel and a lower barrel. There is no indication as to whether

these are the same upper and lower barrels or whether there are two upper barrels and two lower barrels. Furthermore, claim 7 contains the phrase "the lower barrel" and the examiner is unsure as to whether this pertains to the first or second lower barrel in the case that they are different.

6. Claim 1 recites the limitations "the end" and "the upper barrel" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Regarding the above issues, for purposes of examination the examiner has interpreted claim 1 to read "a lower barrel at an end remote from an upper barrel" and claim 2 to read "the upper barrel" and "the lower barrel" as they are recited in claim 1. Therefore, claim 7 is intended to refer to the only lower barrel of the claims as best understood by the examiner.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 2, 4, 5, 7, 9, 11-14, 16-19, 26-31, 34-36, 38, 41-43, 45, 47, 57, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 2,398,544 to Lockhart.

Regarding the above claims, Lockhart teaches a drug delivery device, which can be a single use device, comprising a housing (C); a pre-primed means for generating a force (24); a means for transmitting said force (20); a means for triggering and/or priming the device (S); an upper barrel (26 and C above crosspiece 28) housing the force generating means; a lower barrel (C below crosspiece 28 and 10) housing a packaged drug (A) and the means for transmitting force. Lockhart further teaches a means for receiving the packaged drug (10). Lockhart also teaches that the packaged drug is slidably disposed in the means for receiving the packaged drug (collar 10 slides over the ampoule A), that the means for generating the force is a coil spring (24), and that the force is adjustable by a screw cap and compression bar (cap 26 can screw and

unscrew to change the tension on the spring 24 between it and compression bar 22). Lockhart also teach that the device is primed and actuated by two separate actions (priming by moving the sleeve toward the cap; actuating by moving the sleeve toward the dispensing end), that the drug is in a contained form (A) wherein the drug is a liquid contained by a membrane (A and 18), that the packaged drug is an integral part of the device (without it, no injection can take place), that there is a positive lock retention system (threads, Fig. 2) ensuring the packaged drug does not come away from the device, and that the means for triggering is an actuation button or like element (sleeve S).

Lockhart further teaches a packaged drug comprising a packaging containing a drug comprising a housing (A) having a channel running there through (14), in which is disposed a drive pin (42), a skin piercing means (44) and the drug (44), said housing further comprising a region allowing the packaged drug to be slidably mounted in the drug delivery device (wall of ampoule) and an end adapted to engage and tension the skin (distal end of the ampoule). Lockhart further teaches that the drive pin has a flat head (42), that the means for transmitting the force is a striker (20), that the striker is a hammer (20), wherein a region of the striker is shaped to fit a correspondingly shaped surface in a wall separating the upper and lower barrels (28) such that the striker is aligned to strike the drive pin or other element in the packaged drug on actuation (Figs. 2-3). Lockhart also teaches that the housing is adapted to ensure the packaged drug positively locks to the device yet is free to slide therein (threads, see Fig. 2), that the

packaging is substantially T-shaped (Fig. 2), and that the housing is made up of two parts (A and 18) and holds the drug in a contained state (Fig. 2)

Lockhart also teaches drug delivery via the device described above as shown in Figure 3.

Lockhart fails to explicitly teach or disclose that the velocity of the drug is less than 20 m/s, or moreover less than 10 m/s, or that the delivery force is 10-40N. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the above operating parameters since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Lockhart also fails to explicitly teach or disclose that the wall separating the upper and lower chambers has a frustoconical surface that cooperates with the frustoconical shoulder region (40) of the striker. It would have been an obvious matter of design choice to make the interior surface frustoconical, since applicant has not disclosed that doing so solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the straight surfaces explicitly disclosed by Lockhart.

Lockhart also fails to explicitly teach or disclose that the upper and lower housing are made of separate components. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the components separately, since it has been held that constructing a formerly integral structure in

various elements involves only routine skill in the art. Nerwin v. Erlichman, 168 USPQ 177, 179.

Lockhart fails to explicitly teach or disclose that the drug delivery device is packaged in a foil pouch to prevent ingress of moisture, oxygen, etc. However, this is a practice common in the art of drug delivery devices and is therefore considered obvious to one having ordinary skill in the art.

12. Claims 8, 32, 33, 39, 40, 46, and 48-52 rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart as applied to the above claims, and further in view of USPN 4,968,302 to Schluter et al.

Regarding the above claims, Schluter et al further teach a packaged drug containing a skin piercing means (3) which is a needle, that the tip of the needle is positioned a few mm from the end of the packaging such that it is moving when it contacts the skin (Figs. 5a and 5b), and that there end about the exit end of the channel is in the form of an annular ring having an exit with a depth and width from 1.5-6mm (needle creates channel as shown in Fig. 5b). Schluter et al further teach that the needle is disposed in the channel towards an end and a contained liquid drug is disposed in the channel there above (Fig. 5a), and that the contained liquid drug comprises a receptacle slidably disposed and having a puncturable base (29) a top sealable with the drive pin (22) for pushing the receptacle against the needle (Fig. 5a) and the needle into the human or animal body (Fig. 5b). Schluter et al further teach a resilient spacer between the needle and receptacle (29), that the needle is automatically

withdrawn after use (after an injection the needle is inherently removed from the patient), and that the needle is sharp at both its ends (Fig. 5a).

Schluter et al do not disclose a drug splinter or pioneer projectile, however, such injection modes were known in the art of injection at the time of invention and represent a simple substitution of known parts and therefore would have been an obvious variation on the injection cartridge of Schluter et al.

At the time of invention, it would have been obvious to one having ordinary skill in the art to substitute the ampoule of Schluter et al into the drug delivery device of Lockhart because doing so is simply substituting one known drug package for another to achieve the predictable result of injectable drug delivery into a patient.

Allowable Subject Matter

13. Claims 10, 15, 20-25, 44, and 53-56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

14. Applicant's arguments filed August 26, 2009 have been fully considered but they are not persuasive.

15. While Applicant's arguments have been considered, the arguments beginning on page 16, paragraph 3 and continuing to page 18, paragraph 4; as well as page 19, paragraphs 1 and 2, show what Applicant believes to be the benefits of using the

injection device of the instant invention over use of the injection device of the prior art; however, there is no structural difference of the injection device taught by Lockhart from that of the device of the instant claims, as described above. Furthermore, Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the ***language of the claims*** patentably distinguishes them from the references.

16. Regarding applicant's argument that the ampoule can not slide within the device, the examiner disagrees and notes that in order to fix the ampoule to the device, one must first slide it in and therefore it is slidable within the device.

17. Regarding applicant's argument that Lockhart does not teach or suggest any disadvantages to the use of high velocity liquid injectors such as those disclosed by Lockhart and therefore one skilled in the art would not be motivated to adapt the device for different velocities, the examiner disagrees and notes that motivation to improve devices in existence need not be present in the prior art at the time of the prior art invention, but in the references or the knowledge generally available to one having ordinary skill in the art at the time the instant invention was conceived. Therefore, the examiner believes one having ordinary skill in the art at the time the instant invention was made would have recognized any potential deficiencies in the Lockhart reference and sought to improve upon them.

18. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the examiner notes that both Lockhart and Schluter are medicament injectors having similar modes of actuation and are therefore related. Further, although the primary use of Lockhart is as a needleless injector, one of ordinary skill in the art would recognize that it would be possible to provide it with a needled injector in order to provide various benefits available only via needle injection.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
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